

Implementation Primer Overview and Update

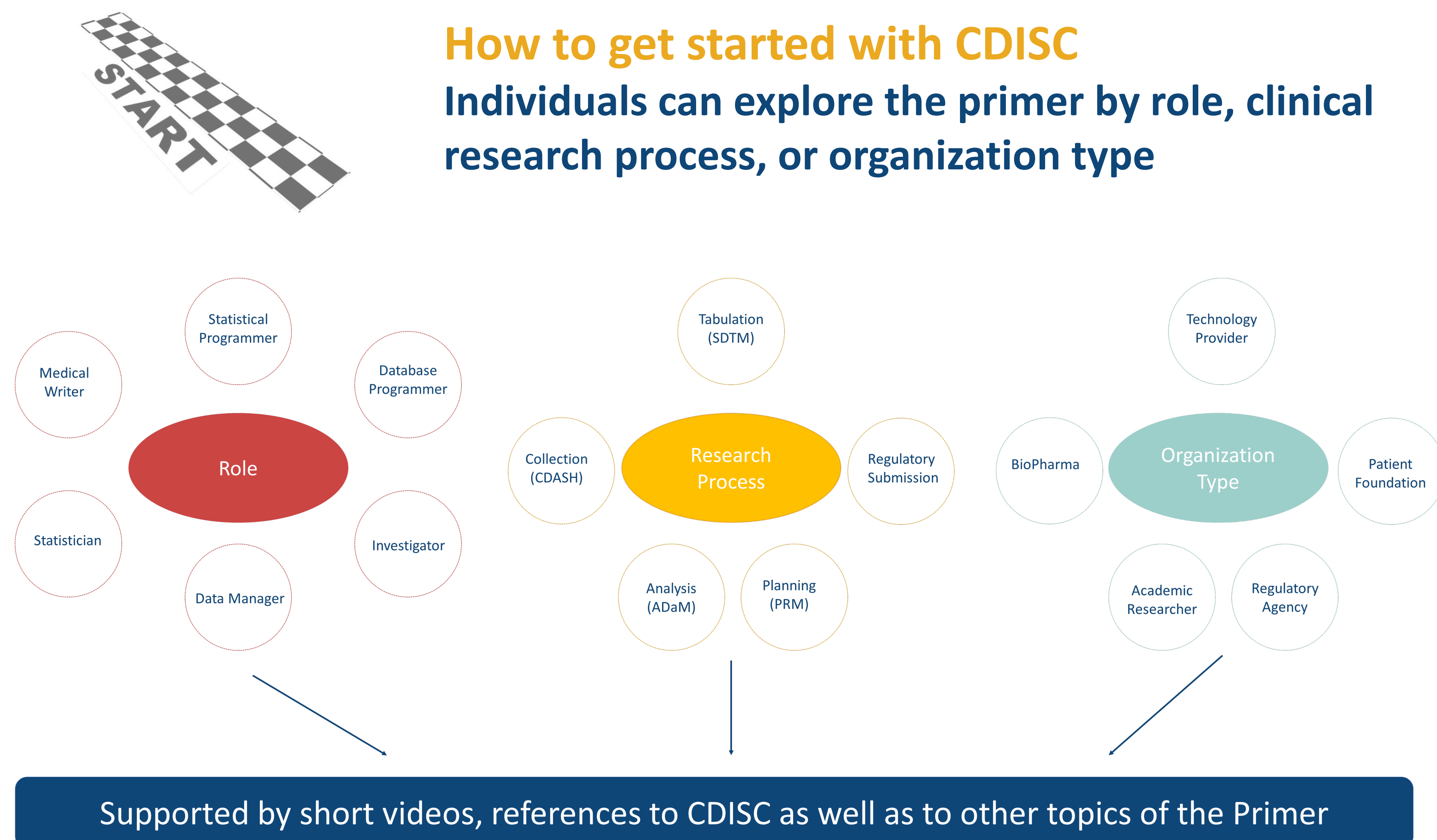
Introduction

As the CDISC implementation community increases, new implementers, especially those not directly connected to the pharmaceutical industry and regulators, need a starting point. The goal of this PHUSE project is to provide new CDISC implementers a freely available primer developed to address these implementation needs.

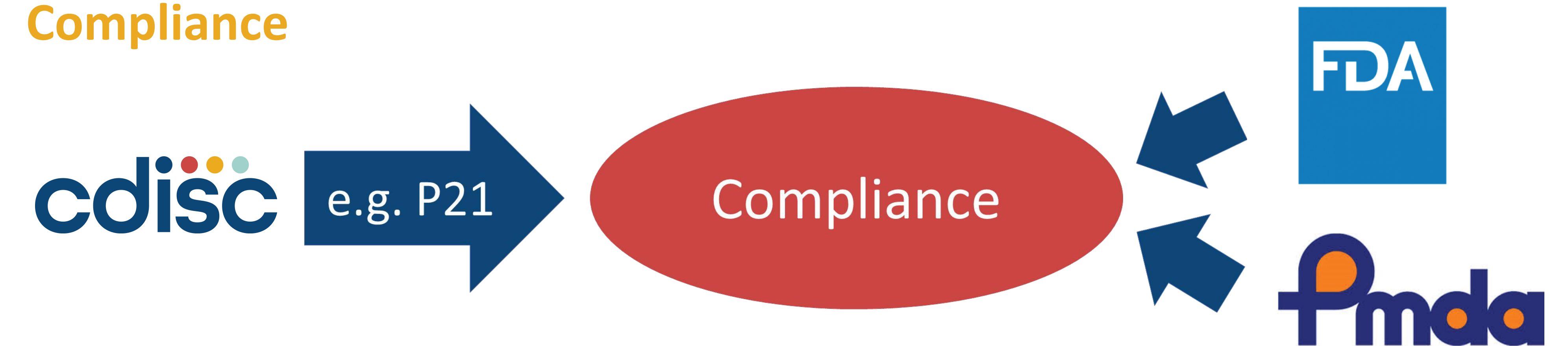
The CDISC Implementation Primer project was launched at the 2018 PHUSE CSS as part of the PHUSE working group “Optimizing the use of Data Standards”, <https://www.phuse.eu/optimizing-data-standards>.

The members of the team decided to first focus on the four topics outlined below.

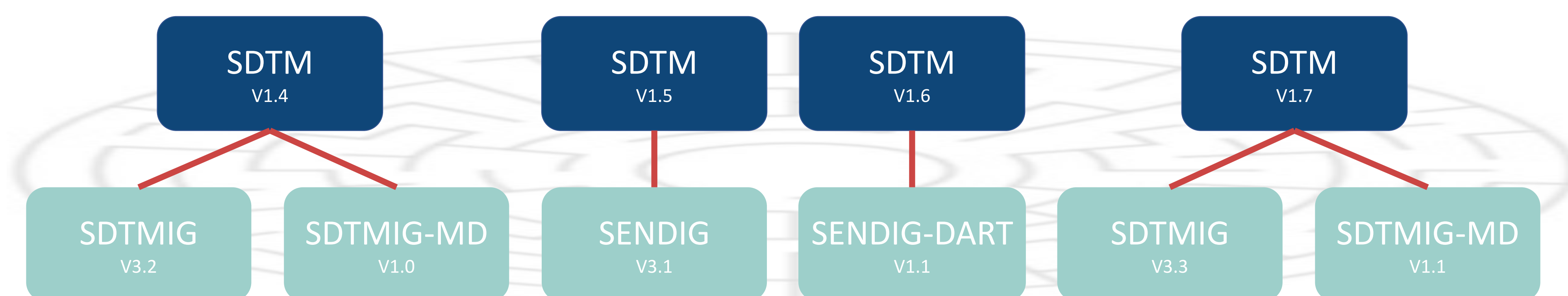
Implementation Primer Topics



Compliance



Understanding the link between the CDISC Standards



Traceability

Documenting the relationships from analysis results to source data as collected is key to ensure traceability on data-point and metadata level.

